REMARKS

Claims 1-14 are extant in the present prosecution, and claims 7-11 are amended herein. Support for the amendment is found in the specification, e.g., p.4:44 and p.9:10-12, and in claims 12-13.

RESTRICTION REQUIREMENT

The examiner's restriction requirement of January 10, 2002 is respectfully traversed, with claims 7-13 being elected. This traversal is based the examiner's misuse of applicants' own claimed product and process to demonstrate "another materially different product" (ppr.4,p.2). The examiner asserts that "a dosage form comprised of an active ingredient such as ibuprofen, acetaminophen, or loperamide" would be a "materially different product" compared to that product of claims 7-13. However, claim 10 is drawn to an oral dosage form comprising active pharmaceutical ingredients, and claim 11 specifically claims oral dosage forms containing ibuprofen, acetaminophen, or loperamide, among other active ingredients. No difference is seen between the asserted "materially different product[s]" (*id.*).

In distinguishing between claims 7-13 and claim 14, the examiner again asserts that "dosage form[s] that can contain famotidine, cimetidine, or ranitidine" are "materially different products" from those in claims 7-13 (ppr.4.p.3). As indicated above, claim 10 is drawn to oral dosage forms containing active pharmaceutical ingredients, and claim 11 also specifically identifies the active ingredients famotidine,

cimetidine, and ranitidine. Again, no difference is seen between these asserted "materially different products" (*id.*).

Finally, the examiner compares the two sets of process claims, claims 1-6 and claim 14, and states that "[s]ince the product is not allowable, restriction is proper between [the] method of making and method of using" (*id.*). The examiner appears to have had completed examination of the product claims prior to requiring restriction. It is highly unlikely that the examiner intended this result, and yet, logically, there can be no other conclusion. Regardless of the intended meaning, however, the standard for restriction has not been established. The two processes "cannot be practiced with ... materially different product[s]," and as shown above, the examiner has used applicants' own claimed examples to show distinctness between the processes and the claimed products. Given the absolute lack of support for the restriction requirement as formulated, applicants simply must respectfully request that the examiner yet again reconsider this requirement, and further request that it be withdrawn and that the claims be considered together in their entirety.

REJECTION UNDER 35 USC §103(A)

Claims 7-9 and 11-13 are not obvious over Wright et al. (US 5,098,714) in view of Cherukuri et al. (US 4,931,293), further in view of Patell (US 4,916,161). To establish *prima facie* obviousness, the examiner must show in the prior art a teaching or suggestion of each claim element, some suggestion or motivation to make the claimed

invention, and a reasonable expectation for success in doing so (*see, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). These requirements have not been met in the examiner's present rejection.

Amended claims 7-11 are drawn to pharmaceutical preparations comprising shaped articles made from a core of an active ingredient and a taste-masking coating. Claims 12-13 are drawn to oral dosage forms which may be produced through compression of these shaped articles. None of the cited references teaches or suggests producing taste-masked shaped articles or oral dosage forms as contemplated by the present claims.

The oral dosage form disclosed in Wright et al. may be given a taste-masking coating, and yet the overall structure of this dosage form would not suggest the presently claimed invention. In Wright, a two-layered active ingredient system is surrounded with a "substantially inert" wall having at least one exit aperture through which the active ingredient passes. Any taste-masking coating would be placed outside this wall, and would cover the entire oral dosage form. Wright teaches a highly specialized active ingredient delivery system, one which does not teach or suggest the presently claimed invention.

As indicated in applicants' previous submissions, Cherukuri teaches a "coating matrix" made by melting and mixing polyvinyl acetate and an emulsifier, and

subsequently adding to this a milled acid powder (col.5:66-col.6-8). In this "matrix," the acid is *embedded* within the polyvinyl acetate mixture and not coated in the manner presently claimed (col.6:26). Cherukuri does not teach or suggest the present invention.

Similarly, the ibuprofen product of Patell is made by "wet granulating [a] combination of ibuprofen and [hydroxypropylmethyl cellulose phthalate]" (col.1:48-49). In this process, the individual components are first combined in a "pregranulation blend," to which the wetting solution is added. The structure of the resulting product would be similar to that obtained in Cherukuri, and does not teach or suggest the present invention. Further, Patell teaches that hydroxypropylmethyl cellulose *phthalate* is useful in taste-masking ibuprofen, rather than hydroxypropylmethyl cellulose itself. One of skill in the art would not be motivated to use a particular compound on the basis of success in using its *phthalate* derivative, absent further reasoning.

Applicants respectfully request that the rejections of claims 7-9 and 11-13 under 35 USC §103(a) be withdrawn.

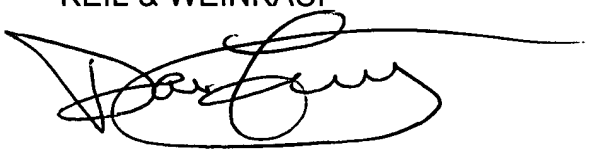
CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

Please charge any shortage in fees due in connection with the filing of this

paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claims 7-11 to read as follows:

7. An oral dosage form preparation comprising shaped articles with an active ingredient-containing core and a taste-masking coating consisting of

a) polyvinyl acetate

b) hydrophilic additives

c) other conventional coating ingredients

d) and, where appropriate, a physiologically tolerated acid or base.

8. An oral dosage form preparation as claimed in claim 7, which comprises the following substances based on the weight of the core

a) 30 to 98% active ingredient

b) 2 to 70% binder

c) 0.1 to 5.0% emulsifier and, where appropriate,

d) 2 to 30% disintegrant

e) and, where appropriate, 0 to 20% of a physiologically tolerated acid or base.

9. An oral dosage form preparation as claimed in claim 7, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.

10. An oral dosage form preparation as claimed in claim 7 [1], which comprises

active pharmaceutical ingredients as active ingredients.

11. An oral dosage form preparation as claimed in claim 7, which comprises as active ingredient acetaminophen, ibuprofen, naproxen, chlorpheniramine, dextromethorphan, acetylsalicylic acid, loperamide, pseudoephedrine, diphenhydramine, famotidine, cimetidine, ranitidine, nizatidine, salts or combinations thereof.

COPY OF ALL CLAIMS

7. An oral dosage form preparation comprising shaped articles with an active ingredient-containing core and a taste-masking coating consisting of

   a) polyvinyl acetate

   b) hydrophilic additives

   c) other conventional coating ingredients

   d) and, where appropriate, a physiologically tolerated acid or base.

8. An oral dosage form preparation as claimed in claim 7, which comprises the following substances based on the weight of the core

   a) 30 to 98% active ingredient

   b) 2 to 70% binder

   c) 0.1 to 5.0% emulsifier and, where appropriate,

   d) 2 to 30% disintegrant

   e) and, where appropriate, 0 to 20% of a physiologically tolerated acid or base.

9. An oral dosage form preparation as claimed in claim 7, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.

10. An oral dosage form preparation as claimed in claim 7, which comprises active pharmaceutical ingredients as active ingredients.

11. An oral dosage form preparation as claimed in claim 7, which comprises as

active ingredient acetaminophen, ibuprofen, naproxen, chlorpheniramine, dextromethorphan, acetylsalicylic acid, loperamide, pseudoephedrine, diphenhydramine, famotidine, cimetidine, ranitidine, nizatidine, salts or combinations thereof.

12. A taste-masked oral dosage form obtainable by compression of at least one preparation as claimed in claim 7 with conventional tablet excipients.

13. A taste-masked oral dosage form as claimed in claim 12, wherein from 0 to 40% of a physiologically tolerated acid or base are added to the tablet mixture.